HFA-305

Approval Date: APR 21 2004

# FREEDOM OF INFORMATION SUMMARY

# SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

# ANADA 200-193

## CLINDAMYCIN HYDROCHLORIDE ORAL LIQUID (clindamycin hydrochloride)

**Indications for use: Expands the dosage range and revises the indications section in dogs and cats.**

**Sponsored by:**

**Phoenix Scientific, Inc.**
**3915 South 48th St. Terrace**
**St. Joseph, MO 64503**

# FREEDOM OF INFORMATION SUMMARY

## *1. General Information:*

| | |
|---|---|
| a. File Number: | ANADA 200-193 |
| b. Sponsor: | Phoenix Scientific, Inc.<br>3915 South 48th St. Terrace<br>St. Joseph, MO 64503<br><br>Drug Labeler Code: 059130 |
| c. Established Names: | Clindamycin hydrochloride oral liquid |
| d. Proprietary Name: | Clindamycin Hydrochloride Oral Liquid |
| e. Dosage Form: | Oral Solution |
| f. How Supplied: | 20 mL (0.68 fl oz) multiple dose vials |
| g. How Dispensed: | Rx |
| h. Amount of Active Ingredients: | Each mL contains clindamycin hydrochloride equivalent to clindamycin 25 mg. |
| i. Route of Administration: | Oral |
| j. Species/Class: | Dogs and cats |
| k. Recommended Dosage: | Dogs: Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb of body weight every 12 hours for a minimum of 28 days.<br>Cats: Wounds, abscesses, and dental infections; 5.0 to 15.0 mg//lb body weight every 24 hours for a maximum of 14 days. |
| l. Pharmacological Category: | Antibacterial |
| m. Indications: | Clindamycin Hydrochloride Oral Liquid is indicated for the treatment of infections caused by |

susceptible strains of the designated microorganisms in the specific conditions listed below:
Dogs: For the treatment of skin infections (wounds and abscess) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphyloccus intermedius)*, deep wounds and abscess due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens,* dental infections due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens,* and osteomyelitis due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens.*

Cats: For the treatment of skin infections (wounds and abscess) due to *Staphylococcus aureus, S. intermedius, Streptococcus* spp., deep wounds and abscesses due to *Clostridium perfringens* and *Bacteroides fragilis,* and dental infections due to *S. aureus, S. intermedius, Streptococcus* spp., *C. perfringens,* and *B. fragilis.*

n. Pioneer Product: ANTIROBE AQUADROPS; Clindamycin Hydrochloride; NADA 135-940; Pharmacia & Upjohn

o. Effect of Supplement: The supplement provides for approval of a dose range and revised indications for use of Clindamycin Hydrochloride Oral Liquid in dogs and cats which was approved for the pioneer product under NADA 135-940 (67 FR 54954, Aug. 27, 2002) with no exclusivity period. The expanded range was changed from a point dose of 2.5 mg/lb. in dogs to an expanded range of 2.5 to 15 mg/lb. The change in cats was from a range of 5.0 to 10.0 mg/lb. to a range of 5.0 to 15.0 mg/lb. The revised indications provides for a change in the words 'soft tissues infections' to 'skin infections' for dogs and cats.

## *2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:*

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Clindamycin Hydrochloride Oral Liquid. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredients. The pioneer product, ANTIROBE AQUADROPS (clindamycin hydrochloride), sponsored by Pharmacia & Upjohn Co., NADA 135-940, was approved on May 23, 1985.

## *3. HUMAN SAFETY:*

This drug is intended for use in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this supplemental ANADA.

## *4. AGENCY CONCLUSIONS:*

This supplemental ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Clindamycin Hydrochloride Oral Liquid (clindamycin hydrochloride), when used under its proposed conditions of use, is safe and effective for its labeled indications.

## *5. ATTACHMENTS:*

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Pioneer Labeling for NADA 135-940:
ANTIROBE AQUADROPS-Insert

Generic Labeling for ANADA 200-193:
Clindamycin Hydrochloride Oral Liquid-bottle label, insert, clipboard carton

# Antirobe®
brand of clindamycin hydrochloride capsules, USP
# Antirobe Aquadrops®
brand of clindamycin hydrochloride liquid

parameters evaluated to assess toxicity when comparing groups of treated animals with contemporary controls Rats administered clindamycin hydrochloride at 600 mg/kg/day (272 7 mg/lb/day) for six months tolerated the drug well, however, dogs orally dosed at 600 mg/kg/day (272 7 mg/lb/day) vomited, had anorexia, and subsequently lost weight At necropsy these dogs had erosive gastritis and focal areas of necrosis of the mucosa of the gall bladder

Safety in gestating bitches or breeding males has not been established

Cat Data: The recommended daily therapeutic dose range for clindamycin hydrochloride (ANTIROBE AQUADROPS Liquid) is 11 to 33 mg/kg/day (5 to 15 mg/lb/day) depending on the severity of the condition. Clindamycin hydrochloride (ANTIROBE AQUADROPS Liquid) was tolerated with little evidence of toxicity in domestic shorthair cats when administered orally at 10× the minimum recommended therapeutic daily dose (11 mg/kg; 5 mg/lb) for 15 days, and at doses up to 5× the minimum recommended therapeutic dose for 42 days Gastrointestinal tract upset (soft feces to diarrhea) occurred in control and treated cats with emesis occurring at doses 3× or greater than the minimum recommended therapeutic dose (11 mg/kg/day, 5 mg/lb/day) Lymphocytic inflammation of the gallbladder was noted in a greater number of treated cats at the 110 mg/kg/day (50 mg/lb/day) dose level than for control cats No other effects were noted Safety in gestating queens or breeding male cats has not been established

## INDICATIONS

ANTIROBE (brand of clindamycin hydrochloride) Capsules (for use in dogs only) and AQUADROPS Liquid (for use in dogs and cats) are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below

**Dogs: Skin infections (wounds and abscesses)** due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*) **Deep wounds and abscesses** due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. **Dental infections** due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. **Osteomyelitis** due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

**Cats: Skin infections (wounds and abscesses)** due to *Staphylococcus aureus, Staphylococcus intermedius, Streptococcus* spp **Deep wounds and infections** due to *Clostridium perfringens* and *Bacteroides fragilis*. **Dental infections** due to *Staphylococcus aureus, Staphylococcus intermedius, Streptococcus* spp., *Clostridium perfringens* and *Bacteroides fragilis*

## CONTRAINDICATIONS

ANTIROBE Capsules and ANTIROBE AQUADROPS Liquid are contraindicated in animals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.

Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas or ruminating animals

## WARNINGS

Keep out of reach of children. Not for human use

## PRECAUTIONS

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed

The use of ANTIROBE occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of ANTIROBE should be avoided in those species sensitive to the gastrointestinal effects of clindamycin (see **CONTRAINDICATIONS**) Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Patients with very severe renal disease and/or very severe hepatic disease accompanied by severe metabolic aberrations should be dosed with caution, and serum clindamycin levels monitored during high-dose therapy.

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, ANTIROBE should be used with caution in animals receiving such agents

Safety in gestating bitches and queens or breeding male dogs and cats has not been established

## ADVERSE REACTIONS

Side effects occasionally observed in either clinical trials or during clinical use were vomiting and diarrhea

To report adverse reactions or a suspected adverse reaction call 1-800-793-0596

## DOSAGE AND ADMINISTRATION

**Dogs:**

**Infected Wounds, Abscesses, and Dental Infections**

Oral: 2.5-15.0 mg/lb body weight every 12 hours

**Duration:** Treatment with ANTIROBE products may be continued up to a maximum of 28 days if clinical judgment indicates Treatment of acute infections should not be continued for more than three or four days if no response to therapy is seen.

**Dosage Schedule:**

**Capsules**

**ANTIROBE 25 mg,** administer 1-6 capsules every 12 hours for each 10 pounds of body weight.

**ANTIROBE 75 mg,** administer 1-6 capsules every 12 hours for each 30 pounds of body weight

**ANTIROBE 150 mg,** administer 1-6 capsules every 12 hours for each 60 pounds of body weight.

**ANTIROBE 300 mg,** administer 1-6 capsules every 12 hours for each 120 pounds of body weight.

**Liquid**

**ANTIROBE AQUADROPS,** administer 1-6 mL/10 lbs body weight every 12 hours.

**Dogs:**

**Osteomyelitis**

Oral: 5.0-15.0 mg/lb body weight every 12 hours

**Duration:** Treatment with ANTIROBE is recommended for a minimum of 28 days. Treatment should not be continued for longer than 28 days if no response to therapy is seen

**Dosage Schedule:**

**Capsules**

**ANTIROBE 25 mg,** administer 2-6 capsules every 12 hours for each 10 pounds of body weight.

**ANTIROBE 75 mg,** administer 2-6 capsules every 12 hours for each 30 pounds of body weight

**ANTIROBE 150 mg,** administer 2-6 capsules every 12 hours for each 60 pounds of body weight

**ANTIROBE 300 mg,** administer 2-6 capsules every 12 hours for each 120 pounds of body weight

**Liquid**

**ANTIROBE AQUADROPS,** administer 2-6 mL/10 lbs body weight every 12 hours

**Cats:**

**Infected Wounds, Abscesses, and Dental Infections**

5 0 - 15.0 mg/lb body weight once every 24 hours depending on the severity of the condition.

**Duration:** Treatment with ANTIROBE AQUADROPS Liquid may be continued up to a maximum of 14 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three to four days if no clinical response to therapy is seen.

**Dosage Schedule:**

**ANTIROBE AQUADROPS,** to provide 5.0 mg/lb, administer 1 mL/5 lbs body weight once every 24 hours; to provide 15 0 mg/lb, administer 3 mL/5 lbs body weight once every 24 hours

## HOW SUPPLIED

ANTIROBE Capsules are available as:

25 mg - bottles of 600 .....NDC 0009-3043-01
75 mg - bottles of 200 .....NDC 0009-3044-01
150 mg - bottles of 100 .....NDC 0009-3045-01
150 mg - blister packages of 100 ..... .NDC 0009-3045-08
300 mg - blister packages of 100 .....NDC 0009-5015-01

NADA #120-161, Approved by FDA

ANTIROBE AQUADROPS Liquid is available as 20 mL filled in 30 mL bottles (25 mg/mL) supplied in packers containing 12 cartoned bottles with direction labels and calibrated dosing droppers, NDC 0009-3179-01.
NADA #135-940, Approved by FDA

To report a suspected adverse reaction or to request a material safety data sheet (MSDS), call 1-800-793-0596.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

ANTIROBE AQUADROPS
Made by
**Pharmacia & Upjohn Company**
Kalamazoo, MI 49001, USA

ANTIROBE Capsules
Made in Canada for
**Pharmacia & Upjohn Company**
Kalamazoo, MI 49001, USA
By **Patheon YM Inc.**
Don Mills, Ontario, M3B 1Y5
CANADA

Revised February 2002

813 805 711
692074
3179-01-000

ANADA 200-193, Approved by FDA

# CLINDAMYCIN HYDROCHLORIDE ORAL LIQUID

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

## DESCRIPTION

Clindamycin Hydrochloride Oral Liquid contains clindamycin hydrochloride which is the hydrated salt of clindamycin. Clindamycin is a semisynthetic antibiotic produced by a 7(S)-chlorosubstitution of the 7(R)-hydroxyl group of a naturally produced antibiotic produced by *Streptomyces lincolnensis var. lincolnensis*.

Clindamycin Hydrochloride Oral Liquid is a palatable formulation intended for oral administration to dogs and cats. Each mL of Clindamycin Hydrochloride Oral Liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

## ACTIONS

**Site and Mode of Action:** Clindamycin is an inhibitor of protein synthesis in the bacterial cell. The site of binding appears to be in the 50S sub-unit of the ribosome. Binding occurs to the soluble RNA fraction of certain ribosomes, thereby inhibiting the binding of amino acids to those ribosomes. Clindamycin differs from cell wall inhibitors in that it causes irreversible modification of the protein-synthesizing subcellular elements at the ribosomal level.

**MICROBIOLOGY:** Clindamycin is a lincosaminide antimicrobial agent with activity against a wide variety of aerobic and anaerobic bacterial pathogens. Clindamycin is a bacteriostatic compound that inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit. The minimum inhibitory concentrations (MICs) of Gram-positive and obligate anaerobic pathogens isolated from dogs and cats in the United States are presented in Table 1 and Table 2. Bacteria were isolated in 1998-1999. All MICs were performed in accordance with the National Committee for Clinical Laboratory Standards (NCCLS).

**Table 1. Clindamycin MIC Values (µg/mL) from Diagnostic Laboratory Survey Data Evaluating Canine Pathogens in the U.S. during 1998-99[1]**

| Organism | Number of Isolates | $MIC_{50}$ | $MIC_{85}$ | $MIC_{90}$ | Range |
|---|---|---|---|---|---|
| Soft Tissue/Wound[2] | | | | | |
| *Staphylococcus aureus* | 17 | 0.5 | 0.5 | ≥4.0 | 0.25->4.0 |
| *Staphylococcus intermedius* | 28 | 0.25 | 0.5 | ≥4.0 | 0.125->4.0 |
| *Staphylococcus* spp | 18 | 0.5 | 0.5 | ≥4.0 | 0.25->4.0 |
| Beta-hemolytic streptococci | 46 | 0.5 | 0.5 | ≥4.0 | 0.25->4.0 |
| *Streptococcus* spp. | 11 | 0.5 | ≥4.0 | ≥4.0 | 0.25->4.0 |
| Osteomyelitis/Bone[3] | | | | | |
| *Staphylococcus aureus* | 20 | 0.5 | 0.5 | 0.5 | 0.5[4] |
| *Staphylococcus intermedius* | 15 | 0.5 | ≥4.0 | ≥4.0 | 0.25->4.0 |
| *Staphylococcus* spp. | 18 | 0.5 | ≥4.0 | ≥4.0 | 0.25->4.0 |
| Beta-hemolytic streptococci | 21 | 0.5 | 2.0 | 2.0 | 0.25->4.0 |
| *Streptococcus* spp. | 21 | ≥4.0 | ≥4.0 | ≥4.0 | 0.25->4.0 |
| Dermal/Skin[5] | | | | | |
| *Staphylococcus aureus* | 25 | 0.5 | ≥4.0 | ≥4.0 | 0.25->4.0 |
| *Staphylococcus intermedius* | 48 | 0.5 | ≥4.0 | ≥4.0 | 0.125->4.0 |
| *Staphylococcus* spp. | 32 | 0.5 | ≥4.0 | ≥4.0 | 0.25->4.0 |
| Beta-hemolytic streptococci | 17 | 0.5 | 0.5 | 0.5 | 0.25-0.5 |

1 The correlation between the *in vitro* susceptibility data and clinical response has not been determined.
2 Soft Tissue/Wound: includes samples labeled wound, abscess, aspirate, exudates, draining tract, lesion, and mass
3 Osteomyelitis/Bone: includes samples labeled bone, fracture, joint, tendon
4 No range, all isolates yielded the same value
5 Dermal/Skin: includes samples labeled skin, skin swab, biopsy, incision, lip

**Table 2. Clindamycin MIC Values (µg/mL) from Diagnostic Laboratory Survey Data Evaluating Feline Pathogens from Wound and Abscess Samples in the U.S. during 1998[1]**

| Organism | Number of Isolates | $MIC_{50}$ | $MIC_{90}$ | Range |
|---|---|---|---|---|
| Bacteroides/ Prevotella | 30 | 0.06 | 4.0 | ≤0.015-4.0 |
| Fusobacterium spp. | 17 | 0.25 | 0.25 | ≤0.015-0.5 |
| Peptostrepto-coccus spp. | 18 | 0.13 | 0.5 | ≤0.015-8.0 |
| Porphyromonas spp. | 13 | 0.06 | 0.25 | ≤0.015-8.0 |

1 The correlation between the *in vitro* susceptibility data and clinical response has not been determined.

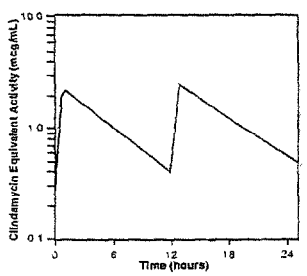
## PHARMACOLOGY

**Absorption:** Clindamycin hydrochloride is rapidly absorbed from the canine and feline gastrointestinal tract.

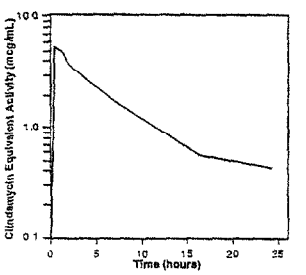
**Dog Serum Levels:** Serum levels at or above 0.5 µg/mL can be maintained by oral dosing at a rate of 2.5 mg/lb of clindamycin hydrochloride every 12 hours. This same study revealed that average peak serum concentrations of clindamycin occur 1 hour and 15 minutes after oral dosing. The elimination half-life for clindamycin in dog serum was approximately 5 hours. There was no bioactivity accumulation after a regimen of multiple oral doses in healthy dogs.

**Cat Serum Levels:** Serum levels at or above 0.5 µg/mL can be maintained by oral dosing at a rate of 5 mg/lb of clindamycin hydrochloride liquid every 24 hours. The average peak serum concentration of clindamycin occurs approximately 1 hour after oral dosing. The elimination half-life of clindamycin in feline serum is approximately 7.5 hours. In healthy cats, minimal accumulation occurs after multiple oral doses of clindamycin hydrochloride, and steady-state should be achieved by the third dose.

Clindamycin Serum Concentrations 2.5 mg/lb (5.5 mg/kg) After B.I.D. Oral Dose of Clindamycin Hydrochloride Capsules to Dogs




Clindamycin Serum Concentrations 5 mg/lb (11 mg/kg) After Single Oral Dose of Clindamycin Hydrochloride Oral Liquid to Cats




## METABOLISM AND EXCRETION

Extensive studies of the metabolism and excretion of clindamycin hydrochloride administered orally in animals and humans have shown that unchanged drug and bioactive and bioinactive metabolites are excreted in urine and feces. Almost all of the bioactivity detected in serum after clindamycin hydrochloride product administration is due to the parent molecule (clindamycin). Urine bioactivity, however, reflects a mixture of clindamycin and active metabolites, especially N-dimethyl clindamycin and clindamycin sulfoxide.

## ANIMAL SAFETY SUMMARY

**Rat and Dog Data:** One year oral toxicity studies in rats and dogs at doses of 30, 100 and 300 mg/kg/day (13.6, 45.5 and 136.4 mg/lb/day) have shown clindamycin hydrochloride to be well tolerated. Differences did not occur in the parameters evaluated to assess toxicity when comparing groups of treated animals with contemporary controls. Rats administered clindamycin hydrochloride at 600 mg/kg/day (272.7 mg/lb/day) for six months tolerated the drug well; however, dogs orally dosed at 600 mg/kg/day (272.7 mg/lb/day) vomited, had anorexia, and subsequently lost weight. At necropsy these dogs had erosive gastritis and focal areas of necrosis of the mucosa of the gall bladder.

Safety in gestating bitches or breeding males has not been established.

**Cat Data:** The recommended daily therapeutic dose range for Clindamycin Hydrochloride Oral Liquid is 11 to 33 mg/kg/day (5 to 15 mg/lb/day) depending on the severity of the condition. Clindamycin hydrochloride oral liquid was tolerated with little evidence of toxicity in domestic shorthair cats when administered orally at 10x the minimum recommended therapeutic daily dose (11 mg/kg; 5 mg/lb) for 15 days, and at doses up to 5x the minimum recommended therapeutic dose for 42 days. Gastrointestinal tract upset (soft feces to diarrhea) occurred in control and treated cats with emesis occurring at doses 3x or greater than the minimum recommended therapeutic dose (11 mg/kg/day; 5 mg/lb/day). Lymphocytic inflammation of the gallbladder was noted in a greater number of treated cats at the 110 mg/kg/day (50 mg/lb/day) dose level than for control cats. No other effects were noted. Safety in gestating queens or breeding male cats has not been established.

## INDICATIONS

Clindamycin Hydrochloride Oral Liquid is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

**Dogs: Skin infections (wounds and abscesses)** due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). **Deep wounds and abscesses** due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. **Dental infections** due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. **Osteomyelitis** due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

**Cats: Skin infections (wounds and abscesses)** due to *Staphylococcus aureus, Staphylococcus intermedius, Streptococcus* spp. **Deep wounds and infections** due to *Clostridium perfringens* and *Bacteroides fragilis*. **Dental infections** due to *Staphylococcus aureus, Staphylococcus intermedius, Streptococcus* spp., *Clostridium perfringens* and *Bacteroides fragilis*.

## CONTRAINDICATIONS

Clindamycin Hydrochloride Oral Liquid is contraindicated in animals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.

Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas or ruminating animals.

## WARNINGS

Keep out of reach of children. Not for human use.

## PRECAUTIONS

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

The use of clindamycin hydrochloride occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of clindamycin hydrochloride should be avoided in those species sensitive to the gastrointestinal effects of clindamycin (see **CONTRAINDICATIONS**). Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Patients with very severe renal disease and/or very severe hepatic disease accompanied by severe metabolic aberrations should be dosed with caution, and serum clindamycin levels monitored during high-dose therapy.

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, clindamycin hydrochloride should be used with caution in animals receiving such agents.

Safety in gestating bitches and queens or breeding male dogs and cats has not been established.

## ADVERSE REACTIONS

Side effects occasionally observed in either clinical trials or during clinical use were vomiting and diarrhea.

## DOSAGE AND ADMINISTRATION

**Dogs: Infected Wounds, Abscesses and Dental Infections**

**Oral:** 2.5-15.0 mg/lb body weight every 12 hours. **Duration:** Treatment with Clindamycin Hydrochloride products may be continued up to a maximum of 28 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three or four days if no response to therapy is seen.

**Dosage Schedule:**

**Clindamycin Hydrochloride Oral Liquid**

Administer 1-6 mL/10 lbs body weight every 12 hours.

**Dogs: Osteomyelitis**

**Oral:** 5.0-15.0 mg/lb body weight every 12 hours. **Duration:** Treatment with Clindamycin Hydrochloride Oral Liquid is recommended for a minimum of 28 days. Treatment should not be continued for longer than 28 days if no response to therapy is seen.

**Dosage Schedule:**

**Clindamycin Hydrochloride Oral Liquid**

Administer 2-6 mL/10 lbs body weight every 12 hours.

**Cats: Infected Wounds, Abscesses and Dental Infections**

**Oral:** 5.0 to 15.0 mg/lb body weight once every 24 hours depending on the severity of the condition. **Duration:** Treatment with Clindamycin Hydrochloride Oral Liquid may be continued up to a maximum of 14 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three to four days if no clinical response to therapy is seen.

**Dosage Schedule:**

**Clindamycin Hydrochloride Oral Liquid,** to provide 5.0 mg/lb, administer 1 mL/ 5 lb body weight once every 24 hours; to provide 15.0 mg/lb, administer 3 mL/5 lbs body weight once every 24 hours.

ANADA #200-193, Approved by the FDA

## HOW SUPPLIED

Clindamycin Hydrochloride Oral Liquid is available as 20 mL filled in 30 mL bottles (25 mg/mL) supplied in packers containing 12 cartoned bottles with direction labels and calibrated dosing droppers.

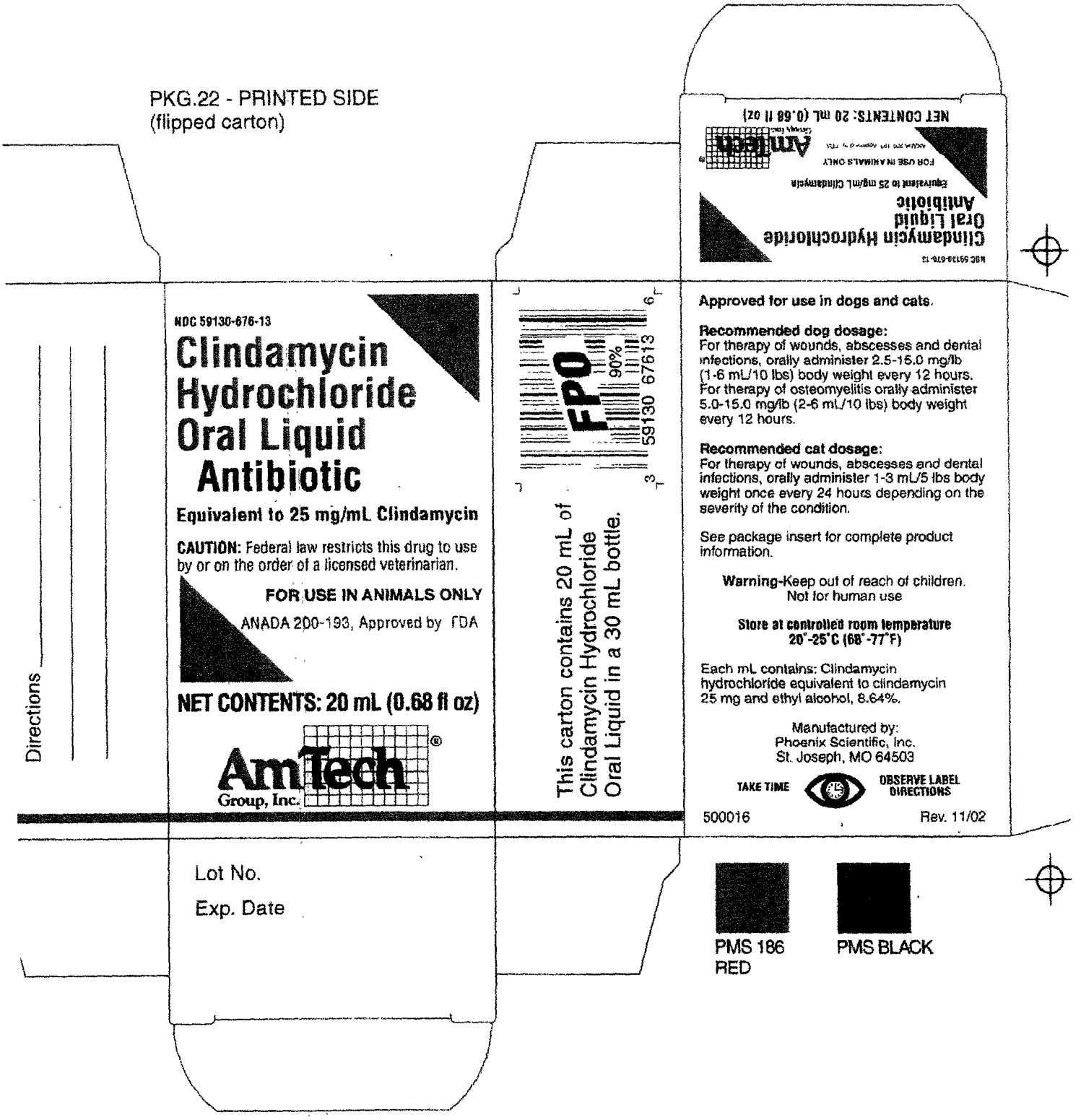
Store at controlled room temperature 20°-25°C (68°-77°F).

500016

Rev. 11/02

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

PKG.22 - PRINTED SIDE
(flipped carton)



Each mL contains: Clindamycin hydrochloride equivalent to clindamycin 25 mg and ethyl alcohol, 8.64%.

See package insert for complete product information.

Manufactured by:
Phoenix Scientific, Inc.
St. Joseph, MO 64503


**Warning**- Keep out of reach of children. Not for human use.

500016 Rev. 11-02

NDC 59130-676-13

# Clindamycin Hydrochloride

## Oral Liquid Antibiotic

**Equivalent to 25 mg/mL Clindamycin**

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**For Use In Animals Only**

ANADA 200-193, Approved by FDA

**NET CONTENTS: 20 mL (0.68 fl oz)**

AmTech® Group, Inc.

**Approved for use in dogs and cats.**

**Recommended dog dosage:** For therapy of wounds, abscesses and dental infections, orally administer 2.5-15.0 mg/lb (1-6 mL/10 lbs) body weight every 12 hours. For therapy of *osteomyelitis orally administer* 5.0-15.0 mg/lb (2-6 mL/10 lbs) body weight every 12 hours.

**Recommended cat dosage:** For therapy of wounds, abscesses and dental infections, orally administer 1-3 mL/5 lb body weight once every 24 hours depending on the severity of the condition.

**Store at controlled room temperature 20°-25°C (68°-77°F)**

Lot No.

Exp. Date